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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,208	07/16/2006	Mark Feldschuh		7784

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EDWIN D. SCHINDLER
FIVE HIRSCH AVENUE
P.O. BOX 966
CORAM, NY 11727-0966

EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,208	FELDSCHUH, MARK	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 11/24/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 6,031,007.

The reference teaches 3 examples in column 4 of anesthetic oral care gel compositions comprising 2.25-2.5% lidocaine (lignocaine), 2.25-2.5% prilocaine, and gelling agents 3.5-5.5% Lutrol F68 and 14-16.25% Lutrol F127 (i.e., POE/POP copolymer). Since local anesthetics by nature have an unpleasant bitter taste, one or more taste masking agents may optionally be added to the pharmaceutical composition. The choice of taste masking agents will be appreciated by a person skilled in the art, but

as an example any fruit flavors may be mentioned (col. 3, ll. 16-21). Since one or more taste masking agents may be added to mask the bitter taste of the local anesthetics and are chosen from fruit flavors, then by choosing any two bitter masking agents according to the teachings in the reference, the requirement for having a flavor and a bitter suppressant present in the composition would be met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/019228 in view of USP 6,031,007.

The primary reference teaches a composition of the invention comprising Poloxamer 407 (a specie of pluronic gel) and lidocaine (Examples 1 and 2, [0066] and

[0070], respectively). Examples of suitable flavoring agents include, but are not limited to, oil of spearmint, peppermint, and wintergreen (¶ [0050]). The reference does not expressly teach the use of a flavor and a bitter suppressing agent used together with the lidocaine and POE/POP copolymer gel.

The secondary references discloses that, since local anesthetics by nature have an unpleasant bitter taste, one or more taste masking agents may optionally be added to a pharmaceutical composition using fruit flavors.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to choose a bitter suppressant such as clove in addition to another flavor as the flavors used in the composition of the primary reference. The artisan would have been motivated to mask the natural bitter flavor of local anesthetics present in the oral gel composition of the primary reference.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/019228 in view of USP 6,031,007, the combination taken in view of USP 5,624,962, US 2003/0180352, and US 2004/0105885.

The disclosure of the primary and secondary references are outlined above. The primary reference further discloses that the composition may further comprise suitable preservatives included, but are not limited to, anti-microbial agents such as chlorhexidine (¶ [0032]). Examples of suitable anti-oxidants include, but are not limited to, sodium bisulfite (¶ [0045]). The reference does not expressly teach sodium

metabisulfite, phenylephrine, ethoxyl diglycol reagent, sodium metabisulfite, lecithin, or isopropyl palmitate/myristate.

The secondary reference discloses an aqueous drug composition having the property of reversible thermosetting gelation for ophthalmic, dermatological and body cavity (e.g., oral – col. 4, line 40) use which comprises effective amount, generally from about 0.001% to about 10% (col. 4, lines 57-58), of drugs (e.g., lidocaine – col. 4, line 52 and Example 6 at col. 8) used for pharmaceutical therapy or diagnosis, methylcellulose, 1.2 to 2.3 (W/V) % of citric acid (i.e., a flavoring; Example 6) and 0.5 to 13 (W/V) % of polyethylene glycol (e.g., PEG 4000; Example 6) (see col.2, lines 35-36), characterized in that said aqueous drug composition is fluid liquid before administration or application and forms gel at a body temperature of a local region immediately after administration or application (abstract). The composition may also comprise from about 0.001% to about 10% of phenylephrine HCl (col. 4, line 7), from about 0.001% to about 10% of chlorhexidine gluconate (col. 4, line 36), and from about 0.001 to 2% of preservatives, solubilizing agents (col. 4, lines 65-67), and surfactants (col. 5, lines 8-9). The reference does not expressly teach the composition as initially being in a gel form. The reference also does not expressly teach ethoxyl diglycol reagent, sodium metabisulfite, lecithin, or isopropyl palmitate/myristate.

The tertiary reference discloses that Transcutol (ethoxyl diglycol reagent) is a known solvent (¶ 0220) and lecithin, isopropyl myristate, and isopropyl palmitate are known surfactants (¶ 0211) used in oral compositions (¶ 0272). The tertiary reference

does not expressly teach each of the other ingredients recited in the claims in combination with the disclosed ingredients.

The quaternary reference discloses that ethoxydiglycol is a known pharmaceutical solvent (¶ [0103]) and sodium metabisulfite is a known pharmaceutical antioxidant (i.e., a preservative) (¶ [0117]). The quaternary reference does not expressly teach each of the other ingredients recited in the claims in combination with the disclosed ingredients.

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. Accordingly, it would have been obvious to add the ethoxyl diglycol reagent as the solubilizing agent, lecithin, isopropyl myristate, and isopropyl palmitate as the surfactants and sodium metabisulfite as the preservative to the composition of the primary reference because each of these ingredients are already known to be used in pharmaceutical compositions for these particular intended purposes (i.e., acting as surfactants, solvents, and preservatives).

As for claim 11, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In this case, the claimed ranges would lie inside result effective ranges taught in the prior art for each ingredient to maintain its effective results as solvents, surfactants, preservatives, flavors, bitter maskers, anesthetizers, gelling agents, decongestants.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is

(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612